

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA LP, ASTRAZENECA  
AB, ASTRAZENECA UK LIMITED, and  
ASTRAZENECA PHARMACEUTICALS  
LP,

Plaintiffs,

V.

WATSON LABORATORIES, INC.,

Defendant.

Civil Action No. 15-1000-RGA  
CONSOLIDATED

Civil Action No. 16-0338-RGA

**PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO  
DISMISS/STRIKE DEFENDANT'S TENTH AFFIRMATIVE DEFENSE AND  
SEVENTH COUNTERCLAIM**

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## **I. INTRODUCTION**

Watson's Opposition to Plaintiffs' Motion to Dismiss/Strike (D.I. 298) rests on two false assumptions: 1) Plaintiffs' March 22, 2017, First Amended Complaint introduced a "new" patent that dramatically changed the scope and posture of this nearly two-year pending litigation; and 2) the Orders of this Court permitted "any Answer" to that Amended Complaint, including thirty-five pages of new counterclaims and defenses that could have been raised at the outset. Because these assumptions are mistaken, Watson's Opposition necessarily fails and Watson's new defenses should be stricken or dismissed.

## **II. ARGUMENT**

### **A. Watson's Untimely Filing Is Inexcusable**

Reflecting the weakness of its legal justification in light of case law precedent, Watson offers self-serving assumptions about its alleged carte blanche right to add new defenses and unsupported attorney argument on the merits. However, Watson's procedural and factual arguments are also both incorrect, and fail to justify their untimely new defenses. Moreover, in addition to being incorrect, Watson's arguments on the merits cannot justify its procedurally improper counterclaims and defenses. *Sirona Dental Sys., Inc. v. Dental Imaging Techs. Corp.*, No. 10-288-GMS, 2012 WL 3929949, at \*6 (D. Del. Sept. 10, 2012) ("[T]he court will grant the plaintiffs' motion to strike.... The court will not address the merits of [the] defense at this time."); *Teva Pharms. USA, Inc. v. Forest Labs., Inc.*, No. 13-2002-GMS, 2016 WL 7325511, at \*1 n.1 (D. Del. Jun. 16, 2016) ("Because the counterclaims are dismissed as untimely, the court need not address whether they are plausibly pleaded.").

### **1. Watson's Alleged "Facts" Justifying Late Defenses Are Incorrect**

Watson's five alleged "pertinent facts" are incorrect and do not justify its late defenses,

which were never authorized.

First, Watson asserts that Plaintiffs “sought Watson’s consent and the Court’s permission to amend their complaint... after the scheduled deadline for the amendment of pleadings.” This is wrong. Plaintiffs approached Defendants more than a week *before* the “scheduled deadline for the amendment of pleadings” and nearly three weeks *after* the USPTO had allowed the claims to extend that scheduled deadline by a month to accommodate the issuance of the reissue patent. (Ex. A.) The Court granted the parties’ stipulated extension of the deadline. (D.I. 147.)

On January 11, 2017, Plaintiffs provided Defendants with drafts of their Amended Complaints (a cooperative effort that no rule required) and sought their consent to file without further burdening the Court with motion practice. (D.I. 279-1, pgs. 11550-65.) Defendants delayed (Exs. B-C), requiring Plaintiffs a meet and confer. The parties held that conference, and later extended the pleadings deadline via a joint stipulation on January 31, 2017, which permitted “any Answer” to the Amended Complaints pursuant to Fed. R. Civ. P. 12(a)(1). (D.I. 160.) A later stipulation with Watson alone permitted an extension of time for Watson’s only. (D.I. 225.) Watson would have the Court believe that these stipulations to extend time combine to grant it the right to file 35 pages of new defenses months after the deadline for amended *pleadings*—but Watson cannot extend a right it never possessed.

Second, Watson claims that the parties had already “agreed in principle” to extend scheduling order deadlines in this case such that there could be no prejudice. (D.I. 298 at 4.) But, there are two gaping holes in this argument. *First*, the Court denied the parties’ request to extend the scheduling deadlines (D.I. 291) *before* Watson filed its Opposition. *Second*, part of the agreement “in principle” was that no new discovery could be served; only existing discovery could be completed (Ex. D at 1 (“As stated in your letter, we understand—and our motion will

indicate—that the extension on the close of fact discovery will allow the parties to complete fact discovery served within the deadlines currently set forth in the Scheduling Order, not to serve additional requests.”)). The *potential* limited extension of fact discovery, therefore, mitigates nothing.

Third, Watson places enormous importance on the *only* non-public document on which its new defense relies. Watson wrongly asserts that this document was produced “after the deadline for substantial completion of document production” (D.I. 298 at 4), when it was actually produced on the January 23, 2017 date for substantial completion—a date extended two months at Defendants’ request. (Ex. E) Watson now insists that this single document provides “key facts” for its new defenses, while ignoring that those “key facts” (a single date) could have been readily ascertained through written discovery months beforehand.

Fourth, Watson insists that Plaintiffs’ Amended Complaint asserted “a new patent, with new claims, accompanied by a new, 3,871-page file history.” These eleventh-hour assertions are simply incorrect. The ’276 patent is not a “new patent”—it is a reissue of the ’060 patent that contained all of the original claims of that patent. *See* 35 U.S.C. § 251(a) (“No new matter shall be introduced into the application for reissue.”). To the extent new claims were added, those claims were necessarily, as a matter of law, *narrower* than any claims already in the case since the reissue occurred more than two years after the original ’060 patent issued. *See* 35 U.S.C. § 251(d) (“No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.”). And Watson omits that 3,500 pages (more than 90%) of the “new, 3,871-page file history” were Information Disclosure Statements and associated documents irrelevant to Watson’s new defenses; the remainder were prosecution documents largely similar to those in the original ’060 file history,

which has been public for over a decade.

Finally, Watson states, without support, that it has “fully complied with its obligations” regarding its invalidity and unenforceability contentions. However, Watson cannot dispute that its contentions lack any mention whatsoever of the new unenforceability positions within its Seventh Counterclaim and Tenth Defense. Watson attempts to explain this discrepancy in a footnote, stating that “[t]he parties are currently negotiating a deadline to supplement contentions and interrogatory responses and Watson intends to add its inequitable conduct defense at that time.” (D.I. 298 at 5 n.2.) No such negotiations regarding “contentions” are underway or have ever taken place.<sup>1</sup> Watson has no justification for its failure to include its unenforceability theories in its contentions, and instead launching an untimely surprise attack with its untimely new defenses. Even if Watson were somehow permitted at this late stage to supplement, which Plaintiffs do not concede, the parties’ “agreement in principle” on schedule extensions would prohibit—and prejudice—Plaintiffs from taking any discovery on these novel and late theories.

## **2. Watson’s Procedural Arguments Provide No Excuse or Recourse**

Watson attempts to dismiss the relevant case law on pleading issues as “purely academic” and mere “statutory parsing.” Relatedly, Watson assumes that this Court expressly granted it the right to file voluminous new counterclaims as a matter of right and out of time. To this end, Watson relies on the single sentence in the parties’ January 31, 2017, joint stipulation that “any Answer” would be permitted after the initial amended pleadings deadline. (D.I. 160 at ¶ 3.) However, no such grant ever took place.

### **a. Watson Omits A Key Provision Of The Order**

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<sup>1</sup> The parties have discussed a deadline to supplemental responses to “*contention interrogatories*,” not “contentions” *and* “interrogatory responses.” (Ex. D at 2 (regarding “contention interrogatories” in a letter to all Defendants); Ex. F (same).)



Watson repeatedly omits the entirety of the critical provision: “Defendants shall be permitted to file any Answer to the Amended Complaints pursuant to the timelines and provisions provided in Fed. R. Civ. P. 12(a)(1).” *Id.* “Answers,” with a capital “A,” are indeed governed by the “provisions provided in Fed. R. Civ. P. 12(a)(1).” Defenses, which are governed by Fed. R. Civ. P. 8(b)(1) and Fed. R. Civ. P. 12(b), are not governed by those provisions. Nor are counterclaims, which are governed by Fed. R. Civ. P. 13. The only thing that Rule 12(a)(1) governs is an “answer” to a complaint. Accordingly, Plaintiffs did not agree, and the Court did not order, any extension of time expressly permitting Watson to turn that “Answer” into an opportunity to insert new defenses and counterclaims under Rules 8(b), 12(b), 13, or otherwise that are not commensurate with the scope of the amendment.

**b. Answers and Counterclaims Are Different Things**

The cases cited by Watson undercut its argument. Watson’s semantic position rests on “Answer” (with a capital “A”) being indisputably inclusive of defenses and counterclaims. But in the case Watson cites, the New York district court’s decision in *Unigene Labs., Inc. v. Apotex, Inc.*, that court repeatedly differentiated between a defendant’s “answer and counterclaims.” *E.g.*, No. 06-CV-5571, 2010 WL 2730471, at \*1 n.1 (S.D.N.Y. July 7, 2010). The district court dismissed those counterclaims, and the Federal Circuit unanimously affirmed (irrespective of Watson’s plea that it did so “with virtually no substantive analysis”). *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1355 (Fed. Cir. 2011).

**c. Delaware Case Law Supports Plaintiffs, Not Watson**

Watson then relies on its alleged carte blanche to file new defenses months late, without seeking leave from the Court, to sidestep the other Delaware cases on point cited by Plaintiffs. According to Watson, it should escape the holding of *Teva* because its new defenses were “expressly permitted,” were filed “months” before trial, and “will likely involve minimal (if any)

expert testimony.” (D.I. 298 at 7-8.) This attorney argument falls apart in light of Watson’s misinterpretation of the January 31, 2017 stipulation. The same conclusion follows for *Sirona*, which Watson tries to distinguish due to its “prompt [ ] filing” of its new defenses and the changed “scope of the case” predicated by the substitution of the ’276 patent for the ’060 patent in Plaintiffs’ Amended Complaint. Watson does not offer—nor can it—any explanation for how belated filing of new defenses resting almost completely on documents publicly available for more than a decade is “prompt.” And as discussed above, Watson’s contention that the reissue patent “changed the scope of the case” is simply incorrect.

Watson’s other cited cases are similarly inapposite. Watson cites this Court’s 2015 decision in *Unimed* as evidence that new defenses may be raised even when a motion for leave to amend a previous answer had already been denied. But the *Unimed* decision involved counterclaims responsive to “newly asserted patents.” *Unimed Pharms. LLC v. Perrigo Co.*, No. 13-236-RGA, 2015 WL 106851, at \*1 (D. Del. Jan. 6, 2015). These were entirely new, distinct patents, not a substituted reissue patent with the same disclosure and original or narrower claims, as is the case here. (Ex. G, Amended Complaint (D.I. 164) at 2, in *Unimed* (asserting eight new patents, none of which were reissue patents).) Watson further tries to point to Delaware’s purported “settled law” in *Standard Chlorine*, *Joseph Bancroft & Sons*, and *Millenium Chemicals* allegedly entitling it to file any response it sees fit after an Amended Complaint. But none of these cases involve patent-related counterclaims. Nor do they explain away the *Teva* and *Sirona* decisions of Delaware courts, which ***prohibited*** counterclaims and defenses outside of the Federal Rules and court scheduling orders. And Watson’s citation to this Court’s decision in *Intercept Pharmaceuticals* does not stand for the premise that “where no prejudice has been (or can be) shown, this Court has permitted amended pleadings,” as Watson asserts. (D.I. 298 at

11.) First, Watson’s 35 pages of new defenses are not “amended pleadings;” they are new causes of action. Second, unlike the plaintiff in *Intercept*, Plaintiffs here *have* alleged prejudice. And this Court’s decision in *Intercept* was predicated on a Fed. R. Civ. P. 15(a) analysis, which is not the present procedural posture before the Court.<sup>2</sup> *Sirona* and *Teva* make clear that new defenses like Watson’s fall outside of the purview of Fed. R. Civ. P. 15(a)(3). *Sirona*, 2012 WL 3929949, at \*2, \*2 n.3; *Teva*, 2016 WL 7325511, at \*1 n.1.

**d. Watson Uses Faulty Facts to Minimize the Prejudice to Plaintiffs**

Watson closes its procedural arguments by dismissing any added burden or prejudice to Plaintiffs and to the Court. Again, these arguments are supported solely by Watson’s selective interpretation of the facts in this case. Watson again relies on its faulty assumptions that it was somehow entitled to file its new defenses the last week of April with the end of fact discovery the first week of June, because this Court “granted Watson leave to file ‘any’ answer” and that the parties “agreed in principle” to extend the schedule. (D.I. 298 at 10.) The Court’s authorization of the parties’ January 31, 2017, agreement cannot be reasonably interpreted as granting “leave” under any Federal Rule other than Fed. R. Civ. P. 12 to Watson—certainly not the leave and good cause under Fed. R. Civ. P. 15 and 16 that *Teva* and *Sirona* dictate are necessary for Watson’s new defenses under this procedural posture. And as has already been noted, the parties’ “agreement in principle” on scheduling was rejected by this Court before Watson filed its counterclaims. (D.I. 291.) That agreement also permitted no new discovery. In essence, Watson elicited an agreement from Plaintiffs that no new discovery could be filed (Ex.

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<sup>2</sup> *Intercept Pharms, Inc. v. Fiorucci*, No. 14-1313, 2017 WL 253966 (D. Del. Jan. 20, 2017). Should the Court seek to undertake evaluation of the *Foman v. Davis* factor test (371 U.S. 178, 182 (1962)) under a Fed. R. Civ. P. 15 analysis, Plaintiffs respectfully request that they be heard on that issue. Several of the *Foman* factors, including undue delay, dilatory motive, futility, and prejudice, are satisfied in this case in favor of AstraZeneca.

D at 1), then sprung new defenses on Plaintiffs knowing they would be immune from written, such as interrogatories and requests for admission, or testimonial discovery on those issues.

Watson also asserts that their new defenses require no new discovery, but cannot speak for AstraZeneca. AstraZeneca would have likely, if permitted, propagated written discovery requests seeking the factual and legal bases for Watson's allegations, and sought corporate witness deposition testimony on those allegations. Watson further alleges there would be no expert discovery on this issue, but this is incorrect and Watson simply has no basis to dictate limits on AstraZeneca's case.

Watson's assertion that "Plaintiffs were previously on notice" of Watson's inequitable conduct allegations because of a notice of an intended subpoena to AstraZeneca's prosecution attorney in March 2017, is baseless. The only inequitable conduct allegation even hinted in the case at that time was related to alleged "fraud" on the USPTO relating to a chemical nomenclature claim construction dispute, which Defendants conceded was no longer at issue on February 10, 2017, before the *Markman* hearing. (Ex. H.) Indeed, if Watson did have its new defenses in mind when it sought the prosecuting attorney's deposition four weeks before its new Answer, there was clearly undue delay and intentionally dilatory motive.

#### **B. Watson's New Defenses Are Legally Insufficient Under FRCP 9(b)**

As discussed previously, the Court need not even review the merits of Watson's new defenses to dismiss them. *Sirona*, 2012 WL 3929949, at \*6; *Teva*, 2016 WL 7325511, at \*1 n.1. In any event, Watson's Opposition improperly relies on attorney argument in an attempt to supplement its legally insufficient pleadings under Fed. R. Civ. P. 9(b), but instead effectively admits to its own pleading failure.

Like its procedural arguments, Watson's arguments on sufficiency and particularity are based on assumptions and inapposite case law. Again, as in its pleading, Watson does little more

than present a historical chronology of events and then concludes that the prosecuting attorney “knew of invalidating information” and “acted with specific intent to deceive the PTO.” (D.I. 298 at 13.) All of this allegedly “invalidating information” was before the PTO during prosecution of the ’276 reissue patent, and yet that patent issued under a different (and expert) examiner than examined the ’060 and ’124 patents. At best, Watson can only speculate that some sort of rejection *might* have been issued by an examiner, which never occurred.

Watson’s arguments on *Exergen*’s “what” factor are unavailing. Watson cites *Teva Parental* and *SunPower* in support of its argument that a blanket, non-specific attack on “all claims” meets *Exergen*’s standard of “which claims, and which limitations in those claims.” *Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1329 (Fed. Cir. 2009). But *Teva Parental* is inapposite because “all claims” had been previously rejected based on *prior art* similar to that omitted—which Watson concedes is not the posture here. *Medicines Co. v. Teva Parenteral Medicines, Inc.*, No. 09-750, 2011 WL 13135647, at \*8-9. And strangely, Watson cites *SunPower Corp. v. PaneClaw, Inc.*, No. 12-1633, 2016 WL 5107029 (D. Del. Sep. 19, 2016) in support of its arguments, then states “[t]hat case is inapposite.” (D.I. 298 at 15.) As for *Exergen*’s “when” factor, Watson’s allegations simply lack the specificity required by the case law. That law, including Watson’s *Cornell* case, requires “specific dates.” *Cornell Univ. v. Illumina, Inc.*, No. 10-433, 2016 WL 3046258, at \*7 (D. Del. May 27, 2016). Those dates are not “uniquely within Plaintiffs’ control.” Watson simply neglected to propound discovery on those topics before the end of fact discovery. As far as pleading specific intent “on information and belief,” this is permitted only when other supporting facts are *in the pleadings*. *Exergen*, 575 F.3d at 1331 n.7 (citing *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990) (“Where pleading is permitted on information and belief, a complaint must adduce specific facts

supporting a strong inference of fraud or it will not satisfy even a relaxed pleading standard.”)); *Kowal v. MCI Commc’n Corp.*, 16 F.3d 1271, 1279 n. 3 (D.C. Cir. 1994) (“[P]leadings on information and belief require an allegation that the necessary information lies within the defendant's control, and ... such allegations must also be accompanied by a statement of the facts upon which the allegations are based.”) An assertion that facts are in control of the other party must be made *in the pleadings*, not buried in an opposition to a motion to dismiss.

In the alternative, Watson seeks leave to amend. (D.I. 298 at 20.) At this late stage, Plaintiffs oppose granting Watson leave to amend, particularly given Watson’s unsupported and open-ended proviso that they may someday “obtain[ ] additional facts that support its claims.” (*Id.*) Plaintiffs respectfully submit that cosmetic updates to Watson’s counterclaims, and the further delay required by briefing on leave to amend, will not resolve the other issues raised in AstraZeneca’s Motion to Dismiss. *Senju* did *not* grant “leave to amend” as Watson alleges; in fact, it denied the underlying motions to dismiss in favor of staying the case in favor of related proceedings. *Senju Pharm. Co. Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 316 (D. Del. 2013). And in *St. Jude*, the motion to dismiss came before the *Markman* hearing at a much earlier stage of the case. (Ex. I at 20-21.) Plaintiffs respectfully request that the Court grant Plaintiffs’ Motion to Dismiss, and do so without granting Watson leave to amend.

### III. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that this Court grant Plaintiffs motion and strike or dismiss, as appropriate, Watson’s Tenth Affirmative Defense and Seventh Counterclaim relating to inequitable conduct.

DATED: June 23, 2017

Respectfully submitted,

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